

### REMARKS

Claims 1, 2, 5-13 and 21-23 remain in the case. Claim 24 has been canceled.

Claims 1, 5 and 6 have been rejected under 35 USC 112 second paragraph. While Applicants disagree, it is believed that the amendment to claim 1 to add that the slight vacuum or pressure is sufficient to provide a visual indication of integrity overcomes this rejection and clearly teaches to one of ordinary skill in the art a standard for ascertaining the request feature and scope of the invention.

Claims 1, 3-6, 8-12, 14-16 have been rejected under 35 USC 102(b) as anticipated by Padgett (US 4,644,586) or by Trewella et al (US 3,073,507). Applicants disagree.

The claims require that a seal be formed between the first and second portion of the bag so that the second section is maintained in a sterile condition. Further, the second section is in a condition of either slight vacuum or slight pressure to provide one with a visual indication of integrity.

The Office Action states that the maintenance of the second section under vacuum or pressure sufficient to provide one with a visual indication of integrity is not a structural element of the invention and merely an intended use of the device and therefore does not limit the bag in any structural way. Applicants disagree. A bag under vacuum or pressure sufficient to provide a visual indication of integrity is a structural limitation on the bag itself. Either it has this feature and hence is integral or it doesn't and is not integral. This is not merely an intended use as alleged by the Office Action is a structural limitation that provides the means for a visual indication of integrity.

As the standard for anticipation is one of strict identity and "the reference must teach every aspect of the claimed invention either explicitly or inherently." (MPEP section 706.02IV, lines 6 and

7) and either cited reference has failed to teach one or more of the claimed elements, neither reference is and cannot be an anticipatory reference. As such, the rejection based on 35 USC 102(b) is respectfully requested to be withdrawn as it fails to provide a reference which contains all of the claimed elements of the present claims and therefore no basis for rejection under 35 USC 102 has been properly made.

Claims 2, 7, 13 have been rejected under 35 USC 103(a) over Trewella et al in view of McDonald (US 6, 030,578). Applicants disagree.

The claims require that the second section of the bag contain sterilized contents and a seal formed between the first and section portion of the bag. Further, the second section is in a condition of either slight vacuum or slight pressure to provide one with a visual indication of integrity.

The office action of June 20, 2007 states at paragraph 9 that Trewella teaches the use of pressure and vacuum during sterilization but the pressure in the bag is brought back to atmospheric at the end of the sterilization and then the bag is sealed. Thus no pressure or vacuum is applied during or after formation of the seal between the two sections.

McDonald is cited for its collar and that according to the Office Action it would have been obvious to one of skill in the art to use the collar as a pressure or vacuum port. MacDonald, like Trewella prefers to use a panel (11) of gas permeable but microbe impermeable material in its bag and then autoclaves the bag to render its contents sterile. In one embodiment the entire bag may be formed of the porous panel material (Column 4, lines 41-44). The panel remains as part of the

bag and thus the bag remains at atmospheric conditions due to the panel's presence. (Column 4, lines 33-54). One of ordinary skill in the art would not have thought to use the collar of MacDonald to form a vacuum or pressure port in view of the teachings of MacDonald that it prefers to use a gas permeable panel in its bag (and which remains as part of the bag) making such a port irrelevant and useless.

Even in the less preferred embodiments of MacDonald that may use e-beam or other radiation over the "preferred method of achieving sterility" (Column 5, lines 10-11) e.g. autoclaving and hence where there is no necessity for the porous panel, it is silent on the use of vacuum or positive pressure in the bag and fails to teach or suggest the formation of a port in the collar. However, MacDonald does indicate that the collar is subjected to sterilizing radiation while in the docking port and that shadowing is to be avoided in order to ensure adequate sterilization (Column 6, lines 65-67). The addition of a vacuum or pressure port would be contradictory and would lead to shadowing and one of ordinary skill in the art would find no teaching, suggestion or motivation in either reference to add such a port. In fact there are strong indications not to do so in both references in that Trewella has a bag under normal atmospheric pressure and MacDonald prefers to use a porous panel in its bag which likewise renders any port useless.

The Office action has failed to provide any explanation as to how and why one of ordinary skill in the art would decide to add such a port in its statements, just merely asserting that the collar could be capable of such a function.

The Patent and Trademark Office (PTO) bears the burden of initially establishing a prima facie case of obviousness. "First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine what the reference teaches. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references combined) must teach or suggest all the claim limitations."

The motivation to make the claimed invention and the reasonable expectation of success must both be found in the prior art, not the applicant's disclosure. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). The references must be considered as a whole and must suggest the desirability, and thus the obviousness of making the combination. *Hodosh v. Block Drug Co., Inc.*, 229 U.S.P.Q. 182, 187 n.5 (Fed. Cir. 1986); MPEP § 2141.

Neither reference teaches, hints or suggests the use of port to create a bag which is under pressure or vacuum so as to provide a visual indication of integrity. In fact as discussed above the preferred inventions of the references have their bags under normal atmospheric conditions. MacDonald goes even further in preferring to keep the porous panel as part of its bag.

Under 35 U.S.C. 103(a), there must be some objective teaching, suggestion or motivation in the prior art that would have motivated one of ordinary skill in the art at the time the invention was made to arrive at the claimed invention as a whole. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case there is none. The Office Action simply contends that MacDonald could be capable of doing so and that it would have been obvious to do so to the bag of Trewella while ignoring the clear teachings of both. Applicants contend that the finding of obviousness was based on knowledge gleaned only from Applicant's own disclosure, and that this rejection is therefore based on improper hindsight reasoning. Applicants acknowledge that while "[a]ny judgment on obviousness is in a sense

necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." *In re McLaughlin* 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971). [emphasis added]

As such, the prima facie case of obviousness has not been established and the rejection should be withdrawn.

Claims 21-23 have been rejected under 35 USC 103(a) over Padgett or Trewella et al in view of Massage (US 3, 837, 215). Applicants disagree.

Padgett is silent on the use of pressure or vacuum in its system.

Trewella teaches the use of pressure and vacuum during sterilization but the pressure in the bag is brought back to atmospheric at the end of the sterilization **and then the bag is sealed**. Thus no pressure or vacuum is applied during or after formation of the seal between the two sections.

Massage teaches a holding chamber in which a sealed bag is put and then subjected to a vacuum or pressure test to determine whether the bag as made is leakproof. It uses a bag under ambient pressure, not one that has already been pressurized or had a vacuum applied to it. It then pressurizes or applies a vacuum to the ambient pressure bag to sense a difference in the bag dimension and tracks/compares this over time and conditions to indicate a leak.

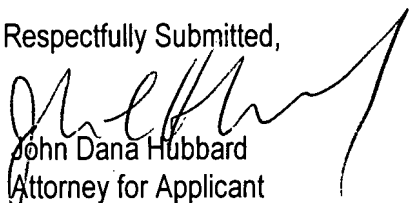
It fails to teach or suggest adding pressure or vacuum to the bag and keeping it there to provide one with a visual indicator of the integrity of the bag during storage, transport and handling

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before use as is available with the present claims. At best, the combination with either reference would provide one who made an ambient pressured bag with an electrical signal indication as to whether the bag was integral at the time of testing. It fails however to provide an ongoing visual indicator as the present invention does. As such either cited combination fails to suggest the present claimed invention.

Reconsideration and allowance of the claims is respectfully requested.

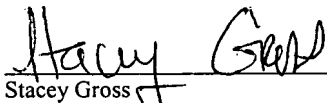
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